

Notice of Allowability

Application No.

10/500,207

Examiner

SHARON WEN

Applicant(s)

TAMURA ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/10/2009.
2. ☒ The allowed claim(s) is/are 11 and 13-15.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 11/19/2009.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Phillip Gambel/
Primary Examiner, Art Unit 1644

/Sharon Wen/
Examiner, Art Unit 1644

DETAILED ACTION

1. Applicant's amendment, filed 11/10/2009, has been entered.
Claims 1-10, 12, and 16-51 have been canceled.
Claims 11, 13, 14 and 15 are pending and currently being allowed.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with B. J. Sadoff on 11/19/2009.

3. The claims have been amended as follows:

-- Claim 11. (Currently Amended) A method of treating arthritis, comprising administering to a patient, as an active ingredient, an antibody which specifically binds to FGF-8 to inhibit activity of FGF-8,

wherein the antibody is a monoclonal antibody selected from an antibody produced by a hybridoma, a humanized antibody and an antigen-binding fragment thereof,

wherein the humanized antibody is a human chimeric antibody or a human complementarity determining region (CDR)-grafted antibody comprising CDRs of VH and VL of a monoclonal antibody which specifically binds to FGF-8 to inhibit activity of FGF-8 and CH and CL of a human antibody,

wherein CDR1, CDR2 and CDR3 of VH comprise the amino acid sequences ~~represented by~~ of SEQ ID NOS: 7, 8 and 9 respectively and CDR1, CDR2 and CDR3 of VL comprise the amino acid sequences ~~represented by~~ of SEQ ID NOS: 10, 11 and 12 respectively. --

-- Claim 13. (Currently Amended) A method of treating arthritis, comprising administering to a patient, as an active ingredient, an antibody which specifically binds to FGF-8 to inhibit activity of FGF-8,

wherein the antibody is a monoclonal antibody selected from an antibody produced by a hybridoma, a humanized antibody and an antigen-binding fragment thereof,

wherein the humanized antibody is a human chimeric antibody or a human complementarity determining region (CDR)-grafted antibody comprising CDRs of VH and VL of a monoclonal antibody which specifically binds to FGF-8 to inhibit activity of FGF-8 and CH and CL of a human antibody,

wherein VH comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 18 or 20 and VL comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 19, 21, 42, 43, 44, 45, 46, 47, 50 or 51. --

-- Claim 14. (Currently Amended) The method according to claim 13, wherein the human CDR-grafted antibody is any of the following human CDR-grafted antibodies (a) to (c),

(a) a human CDR-grafted antibody in which VH comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 18 and VL comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 21,

(b) a human CDR-grafted antibody in which VH comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 18 and VL comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 44, and

(c) a human CDR-grafted antibody in which VH comprises ~~an~~ the amino acid sequence ~~represented by~~ of SEQ ID NO: 18 and VL comprises an amino ~~an~~ the sequence ~~represented by~~ of SEQ ID NO: 50. --

Reason for Allowance

4. The following is an examiner's statement of reasons for allowance:

Applicant's amendment, filed 11/10/2009, has obviated the previous rejection under USC 103(a). Accordingly the presently claimed method of treating arthritis comprising administering the specific anti-FGF-8 antibodies as recited in the claims are free of prior art of record. For the record, it is noted that the antigen specificity of the antibodies recited in claim 15 is to FGF-8 not CH or CL of the human antibody.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
November 19, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
November 22, 2009